08/026,957

UNITED STATES DEPARTMENT OF COMMERCE
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08/026,957	03/05/93	BOYLE	P CL-213

EXAMINER
BUDENS, R

18M2/0419

JAMES A. GIBLIN
ATTORNEY FOR APPLICANTS
MILES INC.
FOURTH & PARKER STREETS
BERKELEY, CA 94701

ART UNIT	PAPER NUMBER
1806	5

DATE MAILED: 04/19/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12-27-93 (1-7-94) ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892. 1 page
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-14 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-14 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☒ The proposed ~~additional~~ or substitute sheet(s) of drawings, filed on 12-27-93 has (have) been ☒ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Examiner acknowledges Applicant's Amendment, Paper No. 3, filed December 27, 1993, and the Supplemental Response, Paper No. 4, filed January 7, 1994. In view of Applicant's Amendment, the status of the claims is as follows: Claims 1-14 are currently pending before the Examiner.

The rejection of claims 1-10 and 12-14 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicant's amendment to the claims.

The rejection of claim 12 under 35 U.S.C. § 102(b) as being clearly anticipated by Bringman et al. (R) is withdrawn in view of Applicant's amendment to the claims.

The rejection of claim 12 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over either Socher et al. (S) is withdrawn in view of Applicant's amendment to the claims.

The amendment filed December 27, 1993, is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment at page 11, line 15, attempts to insert deposit data for the hybridoma designated F448-1D1-A8. However, no reference to F448-1D1-A8 has been found in the specification.

Applicant is required to cancel the new matter in the response to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following rejection constitutes a **new grounds** of rejection in this application necessitated by Applicant's filing of Continuation-In-Part application U.S.S.N. 08/145,060.

Claims 1-14 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-14 of copending application Serial No. 08/145,060. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The rejection of claims 1-14 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility is maintained for the reasons of record set forth in the last Office Action. Applicants' arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant argues that "one skilled in the art would readily recognize the value of any monoclonal antibody directed to a specific substance such as TNF" (see Paper No. 3, page 4, first paragraph). This is not persuasive. The fact remains that Applicant's specification does not expressly disclose any utility for the claimed invention and Applicant has failed to point out to the Examiner where in the specification such a statement of utility exists. Applicant's situation is similar to that in In re Kirk and Petrow, 153 USPQ 49 at 52 (CCPA 1967). There, as here, no specific use for the claimed invention was set forth and Applicant's attempted reliance on the relation of the claimed steroids to previously known steroids was not persuasive to overcome the rejection. Here, Applicant has failed to set forth any teaching of utility for the claimed antibodies and has thus failed to meet his burden under 35 U.S.C. § 101 and 112, first paragraph, to teach how to use the claimed invention. For the above reasons, the rejection is maintained.

The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or

use the invention, i.e. failing to provide an enabling disclosure for the reasons set forth in the last Office Action and set forth above in maintaining the rejection under 35 U.S.C. § 101. Applicant has not set forth any evidence to establish a teaching of utility in the instant application and, thus, has failed to teach one skilled in the art how to use the claimed invention.

Claims 1-14 remain rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure with respect to the requirement for deposit of microorganisms for the reasons set forth in the last Office Action. Applicants' arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant's evidence in the form of ATCC deposit contracts indicates that the deposits were made after the effective filing date of the instant application. In such a case, a further verified statement setting forth a chain of custody is required. Applicant's attention is directed to the last Office Action, page 7, lines 18-26.

Claims 1-14 remain rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure with respect to the scope of the claims for the reasons of record set forth in the last Office Action. Applicant has not responded to this objection or the rejection of the claims. As stated previously, Applicant's antibodies are derived from a single

cytomegalovirus (CMV)-infected donor. The significance of the donor is at question both by the Examiner in the last Office Action and by Applicants themselves in the specification (see page 37, lines 6-7). Thus, the "starting material," i.e. a CMV-infected human lymphocyte donor having autoantibodies to human TNFα, would appear to be a critical factor necessary for reproducing the antibodies of the claimed invention. However, there is no evidence in the record to establish that other such donors are available. As stated previously, it is well known in the art that the production of monoclonal antibodies is unpredictable and that there is a low probability of obtaining the same or similar monoclonal antibodies to a particular antigen. This low probability, together with the characteristics of the B5 human monoclonal antibody, would not allow one skilled in the art to produce the monoclonal antibodies of the claimed invention or similar antibodies without undue experimentation. This lack of enablement is compounded by the fact that Applicant required a CMV positive donor (see page 11, lines 4-14) and that "it is unclear whether or not the CMV seropositive donor origin of B5 mAb is significant" (see page 37, lines 6-7). Thus, it is not clear from the teachings of the specification that one of ordinary skill in the art could obtain additional peripheral blood lymphocytes necessary for human hybridoma production, or even what criteria would be significant for identifying potential lymphocyte donors having anti-TNF human antibodies. As the claims must be commensurate in scope with the enablement provided by the specification, the claims should be limited to the B5 hybridoma producing the B5 human monoclonal antibody to TNFα. Applicant should consider submitting evidence that other CMV-infected human lymphocyte donors yield lymphocytes which produce autoantibodies to TNFα as evidence of the availability of additional "starting material." In the absence of such evidence, the rejection is maintained.

Claims 1-14 appear free of the prior art. The prior art does

not appear to disclose the production of human monoclonal antibodies to human TNFα as set forth in the instant application.

The following art made of record and not relied upon is considered pertinent to applicant's disclosure. Boyle et al. (RR) and Boyle (SS) are Applicant's own publications disclosing the human monoclonal antibodies of the instant application. The references were published after the filing date of the instant application and do not represent prior art to the instant application.

No claim is allowed.

Applicant's amendment and the filing of Continuation-In-Part application U.S.S.N. 08/145,060 necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers relating to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax

Center number is (703) 308-4227. Papers may be submitted Monday-Friday between 8:00 am and 4:45 pm (EST). Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Budens whose telephone number is (703) 308-2960.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert D. Budens
Patent Examiner
Art Unit 1806

rdb
April 15, 1994